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10/721,892

11/26/2003

Mathias Alterman

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5982

7590

07/26/2006

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EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/721,892

Applicant(s)

ALTERMAN ET AL.

Examiner

Laura L. Stockton, Ph.D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 17, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 6-8, 28-31 and 36-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 9-17, 19-27 and 32-35 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/26/03&4/5/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1626

DETAILED ACTION

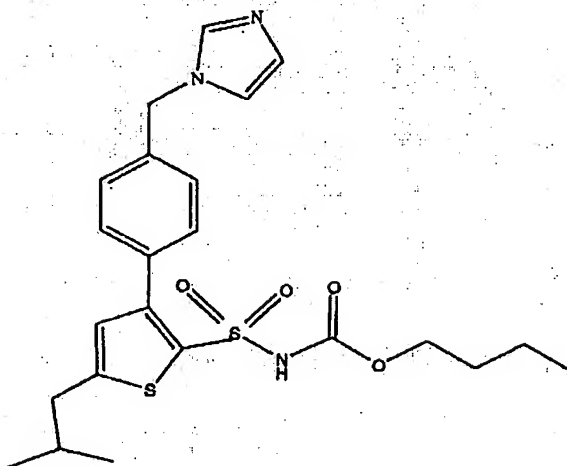
Claims 1-41 are pending in the application.

Election/Restrictions

Applicants' election with traverse of IV (claims 1, 5, 9-27 and 32-35), and the species found on page 34, lines 12-13 (reproduced below) in the reply filed on May 17, 2006 is acknowledged.

Example 1

N-Butyloxycarbonyl-3-(4-imidazol-1-ylmethylphenyl)-5-iso-butylthio-
phene-2-sulfonamide



The traversal is on the ground(s) that: (1) no question of unity of invention rejection was raised in

PCT/GB02/02563; and (2) a 31-way restriction requirement is extremely surprising and believed unnecessary.

In response, the Examiner is not bound by the decisions made in the International phase of an International application. Further, the instant application is a CIP of PCT/GB02/02563. Further, the instant claims embrace a multiple of inventions. The claims are directed to patentably distinct compounds, methods of use, methods of making and various formulas embracing various intermediates (i.e., compounds of Formula V as found in Group XX and on page 11 of the instant specification). Therefore, Applicants' arguments are not persuasive.

Applicants argue that Groups I through V relate to compounds having a tetrazole, 1,2,4-triazole, pyrazole, imidazole and 1,2,3-triazole ring and Applicants consider these separate inventions unified and that a prior art search would identify compounds of Formula I

Art Unit: 1626

in which the requisite nitrogen-containing ring is tetrazole would also identify compounds which are 1,2,4-triazoles, pyrazoles, imidazoles, and 1,2,3-triazoles. Applicants argue that the compounds have structural unity and are also effective and/or selective AT₂ receptor agonists. Applicants argue that structural differences between the final products of formula I and the various intermediates of Formulas II, V, etc. Applicants inquired whether or not the intermediates would be rejoined. Applicants has suggested a three-way restriction opposed to the 31-way restriction.

All of Applicants' arguments have not been considered but have not been found persuasive. It is disagreed that a prior art search would identify compounds of Formula I in which the requisite nitrogen-containing ring is tetrazole would also identify compounds which are 1,2,4-triazoles, pyrazoles, imidazoles, and 1,2,3-triazoles. Note that the cited

Art Unit: 1626

prior art only teaches the elected Group IV imidazole ring (see below art rejection). Separate search considerations are involved for each of the patentably distinct heterocyclic rings. Also, independent claim 1 has provisos which also complicate the type of search and consideration for each potential prior art reference. Therefore, it would be a burden for the Examiner to search, independently, each and every one of the inventions embraced by the current claims.

Applicants have suggested a three-way restriction in opposed to the 31-way restriction. In response, a three-way restriction would put an untold amount of burden on the Examiner whose time is very limited, less than a 8-hour day to examine an application (including searching and the preparation of an Office Action). However, the Examiner would be receptive to other suggestions (i.e., possibly combining one or two other final product groups with the elected invention of Group IV) for restricting the instant application but

Art Unit: 1626

with the understanding that prosecution will not be extended. Additionally, as stated in the Restriction requirement on page 12, Applicants can state clearly on the record that the compound groups are not patentably distinct.

Further, the intermediates were restricted out because the intermediates are not embraced by independent claim 1. Intermediates are not subject to rejoinder because the intermediates do not have all of the limitations of any allowed final products. However, in this case, the Examiner will delay the decision on the intermediates until such a time if the final products are indicated as allowable.

The requirement is still deemed proper and is therefore made FINAL.

Subject matter not embraced by elected Group IV and Claims 2-4, 6-8, 28-31 and 36-41 are withdrawn from

Art Unit: 1626

further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions. Applicant timely traversed the restriction (election) requirement in the reply filed on May 17, 2006.

It is suggested that in order to advance prosecution, the non-elected subject matter be canceled when responding to this Office Action.

In accordance with M.P.E.P. §821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder

Art Unit: 1626

in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Priority

Acknowledgment is made of applicant's claim for foreign priority based on applications filed in the United Kingdom on May 31, 2001, September 7, 2001 and January 26, 2002. It is noted, however, that applicant has not filed certified copies of the United Kingdom applications as required by 35 U.S.C. 119(b).

Information Disclosure Statement

The Examiner has considered the Information Disclosure Statement(s) filed on November 26, 2003 and April 5, 2004.

Art Unit: 1626

Claim Objections

Claims 23 and 26 are objected to because of the following informalities:

a) in claim 23, an "and" is needed before the definition of R⁶; and

b) in claim 26, typographical errors in the nomenclature {i.e., spacing, dashes or parenthesis} need to be corrected in the 2nd, 4th, 5th, 6th and 13th compounds listed in the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1626

Claim 9 lacks antecedent basis from claim 1 (note CF₃ in claim 9).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5, 9-17, 19-27 and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kleemann et al. {U.S. Pat. 6,335,451} in view of Corbier et al. {U.S. Pat. 5,807,878}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim imidazole compounds. Kleemann et al. teach imidazole compounds that are structurally similar to the instant claimed compounds and are useful

Art Unit: 1626

in treating, for example, angina pectoris. See in Kleemann et al., for example, formula I in column 1 wherein R1, R2, R3, R4 and R5 each represent is hydrogen (columns 1-2; columns 14-20; and especially the particularly preferred compounds starting at column 4, line 15).

***Ascertainment of the difference between the prior art and the claims
(MPEP §2141.02)***

The difference between the compounds of Kleemann et al. and the compounds instantly claimed is that Kleemann et al. do not teach the substituents defined by the instant R⁴ variable. Kleeman et al. teach a sulfonylcyanamide group instead of the various substituents defined by the instant R⁴ variable.

***Finding of prima facie obviousness--rational and motivation (MPEP
§2142-2413)***

However, Corbier et al., also teach imidazole compounds that are useful in treating angina pectoris

Art Unit: 1626

(column 30, lines 10-26) and that are structurally similar to the compounds of Kleemann et al. (column 1). Corbier et al. teach the interchangeability of sulfonylcyanamide group (column 4, line 4) and a substituent embraced of the instant R^4 variable (column 4, line 5).

One skilled in the art would thus be motivated to prepare products embraced by Kleemann et al. especially in view of the teachings of Corbier et al. to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, angina pectoris. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art.

Allowable Subject Matter

The elected species, found on page 34 on lines 12-13 of the instant specification, is allowable over the art of record.

Art Unit: 1626

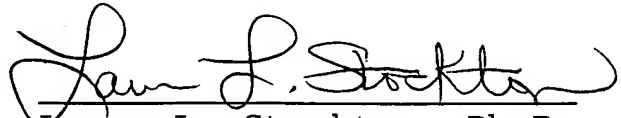
Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if: (1) rewritten in independent form including all of the limitations of the base claim and any intervening claims; and (2) directed solely toward the subject matter of elected Group IV.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 1626

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in cursive script, reading "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

July 21, 2006